

Randomized controlled trial comparing the impact of supplementary feeding with either ready-to-use therapeutic food or corn-soy blend among malnourished anti-retroviral therapy clients in Malawi

Submission date

24/01/2006

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

12/05/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

02/06/2009

Condition category

Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

P.04/05/350

Study information

Scientific Title

Study objectives

Among wasted human immunodeficiency virus (HIV)-infected adults starting anti-retroviral therapy (ART), those that receive short-term, nutrient-dense ready-to-use therapeutic food (RUTF), may show an increase in body weight, experience fewer significant clinical events and higher CD4 counts, than their counterparts that receive corn-soy blend (CSB)

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Malawi College of Medicine Research Ethics Committee (COMREC), reference number: P.04/05/350; Federal Wide Assurance Number 00001395 and registration number 00001157. Also reviewed and approved by the Human Studies Committee, Washington University School of Medicine, St. Louis, Missouri.

Study design

Randomized single-blind (investigator) controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Malnutrition and HIV infection

Interventions

375 g CSB (300 g corn and 75 g soy flour fortified with vitamins and minerals), or 260 g peanut-based RUTF (26% dried skimmed milk, 27% sugar, 26% peanut paste, 20% vegetable oil, and 1.5% vitamins) and mineral premix per person per day during their first three months of ART

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Ready-to-use therapeutic food or corn-soy blend

Primary outcome measure

Body mass index and fat free body mass as measured by the bioelectrical impedance at 3, 6, 9 and 12 months

Secondary outcome measures

1. The number and severity of clinical events at 3, 6, 9 and 12 months
2. Monthly change in quality of life assessment
3. The change from baseline in the CD4 count at three months
4. Serum albumin and hematocrit at three months
5. Viral load at three months
6. Compliance with ART regimen
7. Cost-effectiveness of the two dietary regimens

Overall study start date

06/01/2006

Completion date

06/05/2007

Eligibility**Key inclusion criteria**

1. Adults (>18 years old) diagnosed with acquired immune deficiency syndrome (AIDS) and meeting eligibility criteria for ART according to the National HIV treatment guidelines
2. World Health Organisation (WHO) stage III or IV or any WHO stage and a CD4 count <200 /mm³ and beginning treatment with ART with a body mass index (BMI) of <18.5

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

450 (2 groups of 225 each)

Key exclusion criteria

1. Age <18 years
2. Pregnant or lactating women
3. Enrolment in any other supplementary feeding program

Date of first enrolment

06/01/2006

Date of final enrolment

06/05/2007

Locations**Countries of recruitment**

Malawi

United States of America

Study participating centre

Washington University in St. Louis School of Medicine

Missouri

United States of America

63110

Sponsor information**Organisation**

St. Louis Children's Hospital (USA)

Sponsor details

Department of Pediatrics

Division of Emergency Medicine

St. Louis Children's Hospital

One Children's Place

St. Louis

Missouri

United States of America

63110

manary@kids.wustl.edu

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/00qw1qw03>

Funder(s)**Funder type**

Charity

Funder Name

Academy for Educational Development, Washington DC (USA)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 22/05/2009 | | Yes | No |